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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,587	03/15/2004	James C. Weaver	101328-243 (MIT10778L)	1652
21125 7590 01/09/2009 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER MEHTA, BHISMA				
ART UNIT		PAPER NUMBER		
3767				
NOTIFICATION DATE		DELIVERY MODE		
01/09/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/800,587

Applicant(s)

WEAVER ET AL.

Examiner

BHISMA MEHTA

Art Unit

3767

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 3-20 and 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 21, and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Bellhouse et al (U.S. Patent No. 6,010,478). Bellhouse et al disclose the method of modifying or manipulating body tissue by forming at least one microconduit with the steps of accelerating a plurality of microparticles to a velocity that causes the microparticles to penetrate a region of a tissue surface upon impingement of the microparticles on the tissue surface (lines 44-53 of column 5), directing the microparticles towards the region of tissue surface, so as to cause the microparticles to penetrate the tissue (lines 22-43 of column 7, lines 6-20 of column 9), and scissioning the tissue with the impinging microparticles. The scissioning of the tissue forms a plurality of free microtissue particles and a microconduit as the particles penetrate through or into the tissue or skin. Bellhouse et al also teach treating an infection by delivering a therapeutic molecule or ion through the tissue (lines 31-64 of column 4, lines 6-20 of column 9, and lines 17-35 of column 10).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellhouse et al in view of Karell (U.S. Patent No. 5,947,956). Bellhouse et al disclose the method substantially as claimed. However, Bellhouse et al are silent on the microconduit being formed through nail tissue. Additionally, even though Bellhouse et al disclose administering at least one therapeutic molecule or ion by directing the therapeutic molecule or ion into at least one microconduit, Bellhouse et al are silent on delivering the therapeutic molecule or ion through nail tissue. Karell discloses a method where microconduits are formed through the nail tissue and therapeutic molecules are administered through the nail tissue (line 63 of column 2 to line 3 of column 3, lines 11-19 of column 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the form the microconduits and to deliver the therapeutic molecule or ion as disclosed by Bellhouse et al through nail tissue as taught by Karell as both Bellhouse et al and Karell disclose methods for treating an infection below the surface of body tissue and Karell teaches that it is well known to form microconduits through the nail tissue and deliver the therapeutic agents through the nail tissue when treating an infection below the nail surface such as for treating onychomycosis.

Terminal Disclaimer

5. The terminal disclaimer filed on September 23 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,706,032 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

6. Applicant's remarks in line 17 of page 8 to line 3 of page 9, filed September 23 2008, have been fully considered. In response, claims 1 and 2 are considered to be generic and upon allowance of a generic claim or claims, rejoinder of the withdrawn claims will be considered.

7. Applicant's arguments filed September 23 2008 have been fully considered but they are not persuasive. Applicant's arguments in line 17 of page 9 to line 12 of page 12 with regards to the method step of scissioning the tissue with the impinging microparticles, thereby forming a plurality of free microtissue particles, and thereby forming a microconduit are not persuasive. With regards to the arguments in lines 4-11 of page 10, the definition of scissioning used by the Examiner refers to the act of cutting, separating, dividing, or splitting which is disclosed by Bellhouse et al (lines 50-65 of column 1, lines 44-53 of column 5, and lines 6-20 of column 9). Applicant refers to paragraphs [0068] and [0069] of the specification for the definition of scissioning as being both cutting and removing the small particles of cut tissue. However, in paragraph [0069], it is stated that, according to an embodiment of the invention,

scissioning or microscissioning is a "process of cutting, or microcutting, or cleaving the tissue, thereby forming a plurality of free microparticles of tissue, and thereby forming a microconduit". It should be noted that this definition of scissioning given in the paragraph cited by Applicant has no reference to and does not pertain to removing small particles of cut tissue. In addition, claim 1 is drawn merely to scissioning which has been interpreted to represent cutting, separating, dividing, or splitting as there is no specific mention of the act of removing the small particles of cut tissue in the claim. As to Applicant's arguments in lines 12-29 of page 10, the particles of Bellhouse are capable of scissioning or cutting tissue upon contact as they are accelerated at sufficient velocities to travel through the skin and tissue (lines 6-20 of column 9). Furthermore, claim 1 is not drawn to cutting and removing tissue as these limitations are not found in the claim. In response to applicant's argument in lines 1-22 of page 11 that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the velocity of the particles that cause scissioning) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767